



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/009,213	01/20/98	STYCZYNSKI	P 00216/414001

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HM42/1027

EXAMINER

COOK, R

ART UNIT

PAPER NUMBER

1614

3

DATE MAILED:

10/27/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/009213

Applicant(s)

Styczynska et al

Examiner

Covh

Group Art Unit

1614

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-39 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) 1-39 is/are allowed.
- ☒ Claim(s) 1-39 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 2
- ☐ Interview Summary, PTO-413
- ☒ Notice of References Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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Claims 1-2, 20-39 are generic to a plurality of disclosed patentably distinct species comprising the enzyme system activated and the compound which activates it. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Mr. R. Nabinger on October 14, 1998 a provisional election was made with traverse to prosecute UGT and ethoxyquin. Affirmation of this election must be made by applicant in replying to this Office action.

The disclosure is objected to because of the following informalities: The term UDP is not defined in the specification.

Appropriate correction is required. Support should be submitted that said term may be recognized in the art.

Claims 1-2, 18, 20-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method claim 1 and claim 2 when the androgen is testosterone and the compound induces or activates a UGT, does not reasonably provide enablement for a sulfotransferase or any other enzyme that induces or activates the conjugation of

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any or all androgens. CA125:293042 discloses that sulfotransferase inhibitors inhibit hair growth on an area of the skin from which reduced hair growth is desired.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. While the specification sets forth a method to evaluate whether a compound causes induction of testosterone glucuronide formation, it would require undue experimentation to identify and screen other enzymes and compounds that induce or activate the conjugation of testosterone and other androgens. Limiting the claimed method to "testosterone-stimulation" and "UDP-glucouronosyltrasferase" would overcome this rejection.

Claims 1-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear that the role of the enzyme activated is to metabolize the androgen which causes the undesirable effect to its inactive form. Is the intent of the claims to claim minoxidil, which CA123:4198 discloses is metabolized to its activated form by a sulfotransferase? *amend clarify, NO*

In claims 1 and 17 the term UDP is confusing. The first time an abbreviation appears in a claim it should be preceded by the complete recitation and the abbreviation should follow in parentheses.

Claims to the methods of claims 1 and 2 when the androgen is testosterone and the enzyme is UDP-glucouronosyltrasferase would be allowable.

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Any inquiry concerning this communication should be directed to Examiner Cook at
telephone number (703) 308-1235.

A handwritten signature in cursive script that reads "Rebecca Cook".

**REBECCA COOK
PRIMARY EXAMINER
GROUP 1200**

October 23, 1998